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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,669	08/30/2000	Loren L Roy	17761-000950US	2031

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

LC

Office Action Summary	Application No. 09/651,669	Applicant(s) ROY ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27, 35-39 and 41-46 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>Z</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 36, there is insufficient structure to support the functional limitation of delivering energy to tissue. That is, there is no energy source connected to provide such a function. It is suggested that claim either be amended to clearly recite the energy source to support such a function, or language such as "the electrodes are adapted to transmit" be used to avoid the positive recitation of delivering energy to tissue.

Claim 41 lacks proper antecedent basis for "the limit mechanism". Claim 41 depends from claim 38, and should apparently depend from claim 39 which has proper antecedent basis for the term.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19, 20, 23, 24, 26, 27 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al ('730).

Edwards et al disclose a balloon apparatus which includes a probe with a treatment surface for engaging target tissue, and a plurality of electrodes located on the

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surface (see Figure 3). The treatment surface is an expandable balloon, and the electrodes may be selectively activated (including activating peripherally located electrodes) and are operable in bipolar pairs. Edwards et al further disclose the delivery of a fluid through a conduit. While Edwards et al do not specifically disclose use of the device to shrink collagenous tissue, the examiner maintains that the device delivers energy sufficient to perform such a function. Applicant's recitation of this function is deemed to be a recitation of intended use which bears no patentable weight to the claims as this recitation fails to set forth any structure beyond what is disclosed by Edwards et al. With regard to the specific size of the treatment surface, Edwards et al disclose that the electrode segments (42) are about 1 cm² and about 8mm apart. Figure 3 shows the electrode segments arranged in a 4X7 array which certainly would yield a treatment region having a length of at least 10 mm and a width of at least 5mm.

Claims 19-22, 24-27, 34-39 and 42-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Underwood et al ('961).

Underwood et al disclose an electrosurgical device for the shrinking of collagenous tissue (Abstract). The device includes a thin, flat, rigid surface for contacting tissue, and a plurality of bipolar electrode pairs for delivering energy to tissue (Figure 21B). Underwood et al further disclose a conduit for the delivery of a fluid. Underwood et al disclose that the length of the treatment section may be between 2 and 20mm, and the width in a range from 2 to 10 mm (col. 29, lines 1-20). The electrodes

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are independently controlled such that peripheral electrodes may be energized independently.

Claims 19-22, 24-27, 35-37 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Ingle et al ('238).

The Ingle et al system includes a surface for engaging tissue to shrink collagenous tissue by delivering energy to tissue through a plurality of bipolar electrode pairs (Figure 12). Ingle et al also disclose a conduit for providing a fluid to tissue (Abstract, Figure 1). The electrodes may be independently controlled, and the surface is within the size range set forth in the application claims. With regard to the new limitation specifying the size of the treatment surface, Ingle et al disclose specific size (col. 6, lines 39-42) and spacing (col. 6, lines 63-65 and col. 7, lines 55-57) which clearly make the treatment surface at least 10mm in length and 5mm in width.

Claim Rejections - 35 USC § 103

Claims 21, 25, 42, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al ('730) in view of the teaching of Ingle et al ('238) or Underwood et al ('961).

The Edwards et al device has been addressed previously. Edwards et al fail to disclose the use of a non-ablative energy level and the specific dimensions of the balloon. Ingle et al and Underwood et al both disclose the use of RF energy at non-ablative levels to shrink collagenous tissue. With regard to the dimensions of the balloon, the examiner maintains that one of ordinary skill in the art would recognize the

acceptable range of dimensions which would be appropriate for the treatment of tissue, and that such an acceptable range would fall within the ranges set forth in applicant's claims.

To have provided the Edwards et al system with an RF supply which limited treatment to non-ablative levels for the shrinkage of collagenous tissues would have been an obvious consideration for one of ordinary skill in the art in view of the Underwood et al and/or Ingle et al teachings. To have further provided the Edwards et al balloon with any reasonable size would have been an obvious design consideration for one of ordinary skill in the art.

Claims 25, 38 and 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle et al ('238) in view of the teaching of Underwood et al ('961).

Ingle et al do not expressly state the exact dimensions of the treatment area. Rather, Ingle et al provide a preferred surface area of the treatment area (col. 6, lines 39-42). While the disclosed surface area certainly places the dimensions of the treatment area within the dimensions set forth in claim 19, it is not necessarily the case with the dimensions as set forth in claims 25 and 42. However, the examiner maintains that one of ordinary skill in the art would recognize appropriate dimensions for a treatment area. Underwood et al disclose one such treatment area used to contract tissue which is specifically within the area set forth in claims 25 and 42. Moreover, since the Ingle et al device is used for the exact same procedure as disclosed in the instant application, the examiner maintains that Ingle et al would be well aware of the

appropriate dimensions for the treatment dimensions. Applicant has provided no unexpected result or specific criticality associated with the claimed dimensions of the electrode treatment area.

To have provided the Ingle et al treatment surface with dimension that were specifically within the ranges set forth in the claims to treat tissue would have been an obvious design consideration for one of ordinary skill in the art, particularly since the Ingle et al device is used for the identical procedure as disclosed in the instant application, and further since Underwood et al disclose a device for tissue contraction with a treatment surface having dimensions within the range set forth in the claims.

Response to Arguments

Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive.

Applicant's argument generally relate to the intended use of the device as now recited in the claims. In particular, applicant contends that the Edwards device is directed to a thin layer ablation apparatus, and the presently claimed invention contracts targeted tissue without ablating. It is the examiner's position that the intended use limitation (i.e. to contract tissue) is given minimal weight. The Edwards device is inherently capable of delivering any desired amount of energy such that it may perform the step of tissue contraction, even if that is not the intended function disclosed by Edwards. Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the

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prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, Edwards provides a plurality of electrodes which are adapted to deliver any reasonable level of energy. Applicant has not claimed any specific energy source connected to the electrodes to delivery a specific energy. Rather, the claims merely state that the treatment region is for delivering energy to achieve a desired result. The examiner maintains that the Edwards treatment is capable of this intended result. Further, the examiner has shown where Edwards show support for the treatment region dimensions being within the range as set forth in the claims.

With regard to the Underwood et al system, applicants again contend that the device is for ablation of tissue and that the preferable dimensions of the electrodes are less than 10mm in length and between 2mm and 4mm in width. While the examiner maintains that the use of the Underwood et al device for ablation is immaterial to the rejection, it is pointed out that Underwood et al specifically disclose the device as also being used to contract tissue (Abstract). And, while Underwood et al state that the preferred dimensions are less than 10mm in length and 2mm-4mm in width, it is clearly disclosed that larger dimensions are anticipated. Column 29, lines 1-20 state that the electrodes may be up to 20mm in length and up to 10mm in width.

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Finally, with regard to the Ingle et al reference, the examiner has demonstrated where in the Ingle et al disclosure there is support for the dimension limitations now recited in claim 19.

Allowable Subject Matter

Claim 40 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 41 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

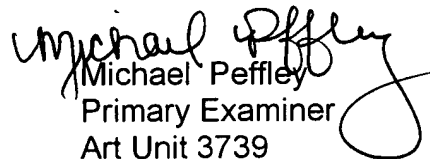
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 21, 2002